

MENTHOL COUGH DROPS- menthol lozenge

Greenbrier International Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Menthol 5.4 mg

Active ingredient (in each drop)

Menthol 5.4 mg

Purpose

Cough suppressant / Oral anesthetic

Uses temporarily relieves:

- cough as may occur with a cold
- occasional minor irritation and sore throat

Warnings

Sore throat warning: is sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have:

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore throat is severe, or irritation, pain or redness lasts or worsens
- sore mouth does not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

adults and children 5 years and over - dissolve 1 lozenge slowly in mouth. Repeat every 2 hours as needed or as directed by a doctor.

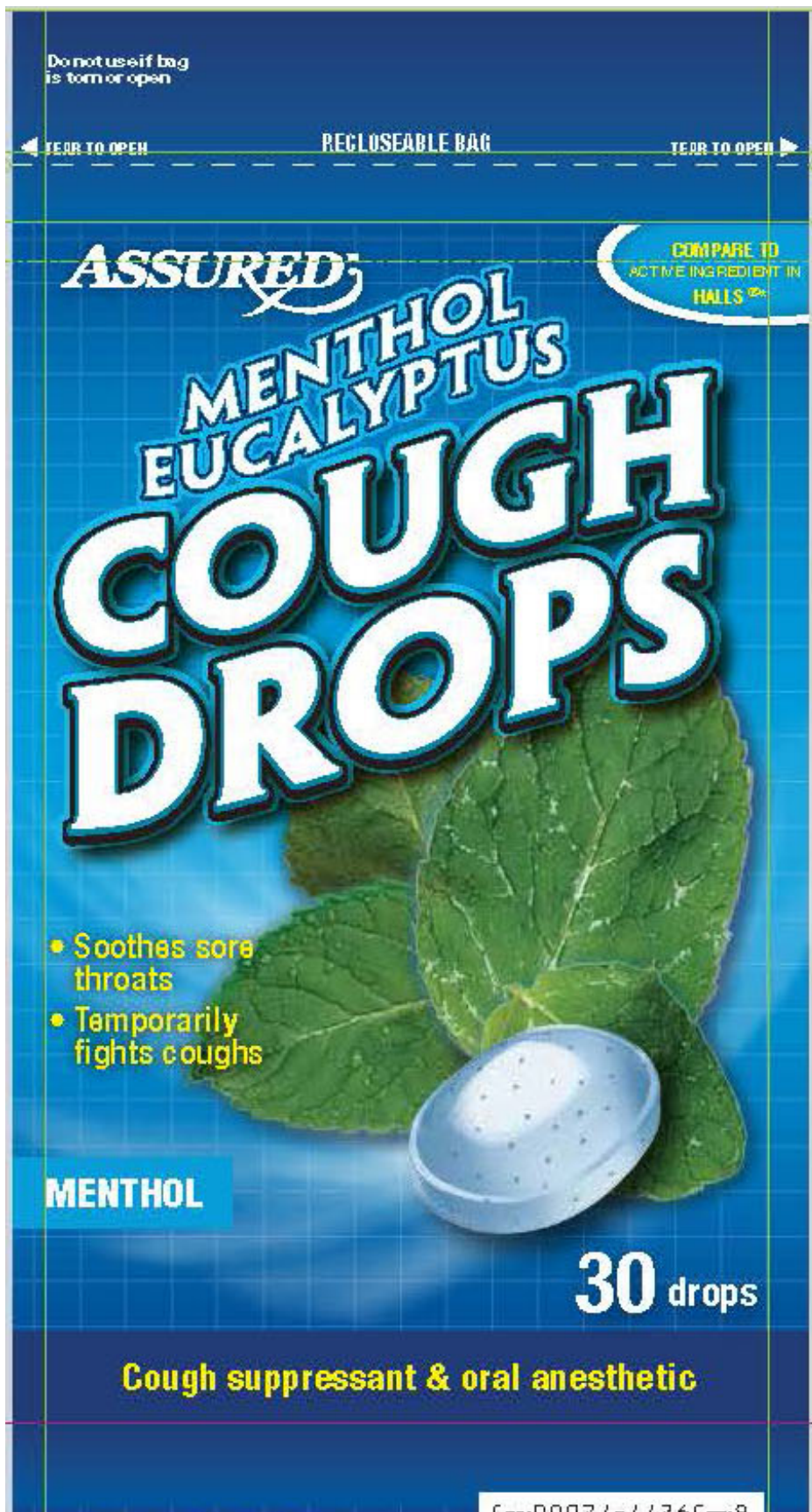
children under 5 years - ask a doctor

Other informatin

- 10 calories per drop
- do not use if bag is torn or open

Inactive ingredients: Corn starch, corn syrup, eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, glycerin, gum arabic, medium chain triglycerides, natural flavor, potassium sorbate, soybean oil, sucrose and water.

Questions? Or to report an adverse event call 1-800-245-2898. Monday - Friday, 9AM to 4PM EST





MENTHOL COUGH DROPS

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-1017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.4 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue (Light Blue with Blue Flakes)	Score	no score
Shape	OVAL	Size	17mm
Flavor	MENTHOL	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-1017-1	30 in 1 BAG; Type 0: Not a Combination Product	12/13/2018	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/13/2018	

Labeler - Greenbrier International Inc. (610322518)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(33992-1017)